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PIONEER HI-BRED INTERNATIONAL INC.
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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,808

Applicant(s)

GORDON-KAMM ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2001.
2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☐ Claim(s) _____ is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-11 and 13, drawn to an isolated nucleic acid, a vector, an expression cassette, a host cell, a transgenic plant, a seed, and a ribonucleic acid, classified in class 536, subclass 23.6, for example.
- II. Claim 12, drawn to an isolated protein, classified in class 530, subclass , 370, for example.
- III. Claims 14-32, 50-53 and 55-60, drawn to methods for modulating the activity of CDK in a plant, improving transformation frequencies and improving transformation by transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter in a sense orientation, classified in class 435, subclass 468, for example.
- IV. Claims 14-32 and 50-60, drawn to methods for modulating the activity of CDK in a plant, improving transformation frequencies and improving transformation by transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter in an antisense orientation, classified in class 800, subclass 286, for example.
- V. Claims 33-38, drawn to a method for modulating the expression of CKI in plant cells by introducing into a plant cell one or more interactors wherein one interactor is a polynucleotide of claim 1 operably linked to a promoter in a sense orientation, classified in class 435, subclass 468, for example.

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- VI. Claims 33-38, drawn to a method for modulating the expression of CKI in plant cells by introducing into a plant cell one or more interactors wherein one interactor is a polynucleotide of claim 1 operably linked to a promoter in an antisense orientation, classified in class 800, subclass 286, for example.
- VII. Claims 33-38, drawn to a method for modulating the expression of CKI in plant cells by introducing into a plant cell one or more interactors wherein one interactor is a polypeptide of claim 12, classified in class 530, subclass 320, for example.
- VIII. Claims 39-44, 61-63 and 66-68, drawn to a method for modulating the activity of CKI in plant cells by introducing into a plant cell one or more interactors wherein one interactor is an antibody directed against maize CKI, classified in class 530, subclass 387.1, for example.
- IX. Claims 39-44, 61-63 and 66-68, drawn to a method for modulating the activity of CKI in plant cells by introducing into a plant cell one or more interactors wherein one interactor is a pharmaceutical directed against maize CKI, classified in class 424, subclass 178.1, for example.
- X. Claims 39-44, 61-63 and 66-68, drawn to a method for modulating the activity of CKI in plant cells by introducing into a plant cell one or more interactors wherein one interactor is a peptide that binds to CKI, classified in class 530, subclass 300, for example.
- XI. Claims 39-44, 61-63 and 66-68, drawn to a method for modulating the activity of CKI in plant cells by introducing into a plant cell one or more interactors wherein

one interactor is an aptamer that binds to CKI, classified in class 514, subclass 44, for example.

- XII. Claims 45-48, drawn to a method for ectopic expression to modulate cell proliferation by transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter in a sense orientation, classified in class 800, subclass 290, for example.
- XIII. Claims 45-48, drawn to a method for ectopic expression to modulate cell proliferation by transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter in an antisense orientation, classified in class 800, subclass 286, for example.
- XIV. Claim 49, drawn to a method for identifying maize CKI interacting proteins, classified in class 536, subclass 23.4, for example.
- XV. Claims 61, 64-65 and 66-68, drawn to a method for improving transformation comprising by introducing into a plant cell with one or more interactors wherein the interactor comprises an antisense oligonucleotide and further transforming the plant cell with a polynucleotide, classified in class 536, subclass 24.5, for example.
- XVI. Claims 69-72, drawn to a method for modulating the cell cycle by transforming a plant cell with a CKI polynucleotide of claim 1, classified in class 435, subclass 468, for example.

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- XVII. Claim 73, drawn to a method for increasing callus growth rate by transforming a plant cell with a CKI polynucleotide of claim 1, classified in class 800, subclass 290, for example.
- XVIII. Claim 74-75, drawn to a method for increasing transformation frequency by transforming a plant cell with a CKI polynucleotide of claim 1, classified in class 435, subclass 468, for example.
- XIX. Claim 76-78, drawn to a method for increasing cell growth rate by transforming a plant cell with a CKI polynucleotide of claim 1, classified in class 800, subclass 290, for example.

For inventions I, III-VI, XIV and XVI-XIX above, restriction to one of inventions (A)-(C) is also required under 35 USC 121. Therefore, upon election of any of inventions I, III-VI, XIV and XVI-XIX, one of inventions (A)-(C) must also be elected.

(A) SEQ ID NO:1 and a polynucleotide encoding SEQ ID NO:2

(B) SEQ ID NO:3 and a polynucleotide encoding SEQ ID NO:4

(C) SEQ ID NO:5 and a polynucleotide encoding SEQ ID NO:6

For inventions II and VII above, restriction to one of inventions (D)-(F) is also required under 35 USC 121. Therefore, upon election of either of inventions II or VII, one of inventions (D)-(F) must also be elected.

(D) SEQ ID NO:2

(E) SEQ ID NO:4

(F) SEQ ID NO:6

Applicants are reminded that nucleotide sequences encoding different proteins, and the amino acid sequences they encode, are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, or the assertion that the sequences are not patentably distinct, each such nucleotide and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions II and VII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation and different functions. The isolated nucleic acid of invention I has a different structure and function than the isolated protein of invention II. Furthermore, the isolated nucleic acid of invention I is not used in the methods of inventions II and VII-XI.

Invention I and inventions III-VI and XII-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

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product (MPEP § 806.05(h)). In the instant case the polynucleotide of invention I can be used in a materially different process of using that product, such as a hybridization method, or a method of producing a recombinant protein.

Invention II and inventions III-VI and VIII- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The isolated protein of invention II is not used in the methods of inventions III-VI and VIII- XIX.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated protein can be used in a materially different process of using that product, as an antigen in an immunoassay, or as an immunogen in an immunization protocol, for example.

Invention III and inventions IV- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention III requires transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter in a sense orientation and the production of a regenerated plant capable of expressing the CKI

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expression product for a time sufficient to modulate CDK activity in the plant, which mode of operation is not required by the methods of inventions IV- XIX.

Invention IV and inventions V- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention IV requires transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter in an antisense orientation and the production of a regenerated plant capable of expressing the CKI expression product for a time sufficient to modulate CDK activity in the plant, which mode of operation is not required by the methods of inventions V- XIX.

Invention V and inventions VI- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention V requires introducing into a plant cell an interactor that is a polynucleotide of claim 1 operably linked to a promoter in a sense orientation and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions VI- XIX.

Invention VI and inventions VII- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention VI

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requires introducing into a plant cell an interactor that is a polynucleotide of claim 1 operably linked to a promoter in an antisense orientation and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions VII- XIX.

Invention VII and inventions VIII- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention VII requires introducing into a plant cell an interactor that is a polypeptide of claim 12 and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions VIII- XIX.

Invention VIII and inventions IX- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention VIII requires introducing into a plant cell an interactor that is an antibody directed against maize CKI and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions IX-XIX.

Invention IX and inventions X- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention IX

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requires introducing into a plant cell an interactor that is a pharmaceutical directed against maize CKI and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions X- XIX.

Invention X and inventions XI- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention X requires introducing into a plant cell an interactor that is a peptide that binds to CKI and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions XI- XIX.

Invention XI and inventions XII- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention XI requires introducing into a plant cell an interactor that is an aptamer that binds to CKI and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions XII- XIX.

Invention XII and inventions XIII- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention XII requires transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter

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in a sense orientation and the production of a regenerated plant capable of ectopic expression of the maize CKI polynucleotide for a time sufficient to modulate cell proliferation in the plant, which mode of operation is not required by the methods of inventions XIII- XIX.

Invention XIII and inventions XIV- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention XIII requires transforming a plant cell with a maize CKI polynucleotide operably linked to a promoter in an antisense orientation and the production of a regenerated plant capable of ectopic expression of the maize CKI polynucleotide for a time sufficient to modulate cell proliferation in the plant, which mode of operation is not required by the methods of inventions XIV- XIX.

Invention XIV and inventions XV- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention XIV requires adducting the nucleic acid sequence of claim 1 to a second nucleic acid sequence encoding a DNA-binding domain, which mode of operation is not required by the methods of inventions XV- XIX.

Invention XV and inventions XVI- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention XV

requires introducing into a plant cell an interactor that is an antisense oligonucleotide and expressing the interactor for a time sufficient to modulate CKI expression in the plant cell, which mode of operation is not required by the methods of inventions XVI- XIX.

Invention XVI and inventions XVII- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention XVI requires transforming a plant cell with a CKI polynucleotide of Claim 1 operably linked to a promoter and the production of a regenerated plant cell capable of expressing the CKI expression product for a time sufficient to modulate CKI activity in the transformed plant cell, which mode of operation is not required by the methods of inventions XVII- XIX.

Invention XVII and inventions XVIII- XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions different modes of operation. The method of invention XVII requires transforming a plant cell with a CKI polynucleotide of Claim 1 operably linked to a promoter and the production of a regenerated plant cell capable of expressing the CKI expression product for a time sufficient to increase the callus growth rate of transformed plant cell, which mode of operation is not required by the methods of inventions XVIII- XIX.

Invention XVIII and invention XIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the

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instant case the different inventions different modes of operation. The method of invention XVIII requires transforming a plant cell with a CKI polynucleotide of Claim 1 operably linked to a promoter and the production of a regenerated plant cell capable of expressing the CKI expression product for a time sufficient to increase transformation frequency in the transformed plant cell, which mode of operation is not required by the method of invention XIX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, their recognized divergent subject matter, and the requirement for different areas of search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

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103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

Cynthia Collins 6/03/04